AUG 17 2004

No. 03-1454

In the Supreme Court of the United States

JOHN D. ASHCROFT, ATTORNEY GENERAL, ET AL.,
PETITIONERS

v.

ANGEL MCCLARY RAICH, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF FOR THE PETITIONERS

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QUESTION PRESENTED

Whether the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, exceeds Congress's power under the Commerce Clause as applied to the intrastate possession and manufacture of marijuana for purported personal "medicinal" use or to the distribution of marijuana without charge for such use.

PARTIES TO THE PROCEEDING

Petitioners are John D. Ashcroft, Attorney General of the United States, and Karen P. Tandy, Administrator of the Drug Enforcement Administration.

Respondents are Angel McClary Raich, Diane Monson, John Doe Number One, and John Doe Number Two.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-43a) is reported at 352 F.3d 1222. The order of the district court denying respondents' motion for a preliminary injunction (Pet. App. 44a-69a) is reported at 248 F. Supp. 2d 918.

JURISDICTION

The judgment of the court of appeals was entered on December 16, 2003. A petition for rehearing was denied on February 25, 2004 (Pet. App. 70a-71a). The petition for a writ of certiorari was filed on April 20, 2004, and was granted on June 28, 2004. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

CONSTITUTIONAL PROVISIONS INVOLVED

The Commerce Clause of the United States Constitution, Article I, Section 8, Clause 3, provides:

> The Congress shall have Power * * * To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.

The Necessary and Proper Clause of the United States Constitution, Article I, Section 8, Clause 18, provides:

> The Congress shall have Power * * * To make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested by this Constitution in the Government of the United States, or in any Department or Officer thereof.

STATEMENT

1. a. The Controlled Substances Act (CSA or Act), 21 U.S.C. 801 *et seq.*, establishes a comprehensive federal scheme to regulate the market in controlled substances. The CSA makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense" any controlled substance, "[e]xcept as authorized by [21 U.S.C. 801-904]." 21 U.S.C. 841(a)(1). The CSA similarly makes it a crime to possess any controlled substance except as authorized by the Act. 21 U.S.C. 844(a). The CSA thus establishes "a 'closed' system of drug distribution" for all controlled substances. H.R. Rep. No. 1444, 91st Cong., 2d Sess. Pt. 1, at 6 (1970). To effectuate that closed system, the CSA "authorizes transactions within 'the legitimate distribution chain' and makes all others illegal." *United States* v. *Moore*, 423 U.S. 122, 141 (1975) (quoting H.R. Rep. No. 1444, *supra*, Pt. 1, at 3). Persons who violate the CSA are subject to criminal and civil penalties, and ongoing or anticipated violations may be enjoined. 21 U.S.C. 841-863, 882(a).

The restrictions that the CSA places on the manufacture, distribution, and possession of a controlled substance depend upon the schedule in which the drug has been placed. 21 U.S.C. 821-829. Since Congress enacted the CSA in 1970, marijuana and tetrahydrocannabinols have been classified as schedule I controlled substances. See Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, § 202, 84 Stat. 1249 (schedule I(c)(10) and (17)); 21 U.S.C. 812(c) (schedule I(c)(10) and (17)).[1]

A drug is listed in schedule I, the most restrictive schedule, if it has "has a high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1)(A)-(C). Under the CSA, it is unlawful to manufacture, distribute, dispense, or possess a schedule I drug, except as part of a strictly controlled research project that has been registered with the Drug Enforcement Administration (DEA) and approved by the Food and Drug Administration (FDA). 21 U.S.C. 841(a)(1), 823, 844(a); *United States* v. *Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 489-490, 492 (2001). By contrast, drugs listed in schedules II through V may be

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[1] Marijuana is defined under the CSA to include all parts of the cannabis plant and anything made therefrom, except for the mature stalks, fiber produced from the stalks, sterilized seeds, and oil from the seeds. 21 U.S.C. 802(16). Marijuana has been found to contain at least 483 separate chemicals, among which delta^9-tetrahydrocannabinol (delta^9-THC) is the primary psychoactive component. 66 Fed. Reg. 20,041 (2001).

dispensed and prescribed for medical use. Manufacturers, physicians, pharmacists and others who may lawfully produce, prescribe, or distribute drugs listed in schedules II through V must, however, comply with stringent statutory and regulatory provisions that control the manufacture and distribution of such drugs. 21 U.S.C. 821-829; 21 C.F.R. Pts. 1301-1306; see pp. 32-33, 39-41, *infra*.

b. The CSA contains congressional findings and declarations regarding the effects of drug distribution and use on the public health and welfare and the effects of intrastate drug activity on interstate commerce. After stating that "[m]any of the drugs included within [the CSA] have a useful and legitimate medical purpose and are necessary to maintain the health and welfare of the American people," 21 U.S.C. 801(1), Congress found that "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people." 21 U.S.C. 801(2). Congress then found:

> A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because—
>
> (A) after manufacture, many controlled substances are transported in interstate commerce,
>
> (B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and

> (C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.

21 U.S.C. 801(3). Congress further found that "[l]ocal distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances," 21 U.S.C. 801(4); that "[c]ontrolled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate" and "[t]hus, it is not feasible to distinguish" between such substances "in terms of controls," 21 U.S.C. 801(5); and that "[f]ederal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic," 21 U.S.C. 801(6).

2. On October 9, 2002, respondents filed suit in the United States District Court for the Northern District of California against John Ashcroft, the Attorney General of the United States, and Asa Hutchinson, then Administrator of the DEA, seeking injunctive and declaratory relief barring those officials from enforcing the CSA with respect to their conduct. The complaint alleges that respondents Angel McClary Raich and Diane Monson are California citizens who use marijuana for medical purposes based on the recommendations of their physicians. Such use is exempted from the coverage of California's criminal drug laws. Pet. App. 1a-2a, 45a; see California Compassionate Use Act of 1996, Cal. Health & Safety Code § 11362.5(b)(1)(A) and (d) (West Supp. 2004) (exempting from the State's criminal laws the possession or cultivation of marijuana for "personal medical purposes" by a patient or her primary caregiver, "upon the written or oral

recommendation or approval of a physician" that marijuana would assist in the treatment of "any * * * illness for which marijuana provides relief").

Raich, a resident of Oakland, California, alleges that she suffers from numerous severe and debilitating medical conditions for which marijuana alone provides relief, and that her physicians recommend that she "medicate" with marijuana every two hours. Pet. App. 5a; J.A. 24, 27. Raich alleges that she is unable to cultivate her own marijuana and that she obtains marijuana free of charge from two "caregivers," respondents John Doe Number One and John Doe Number Two, who are also residents of Oakland, California, and who sued anonymously to protect Raich's marijuana supply. Pet. App. 5a, 14a n.3; J.A. 25-26. Although the Does cultivate the marijuana, Raich processes some of the marijuana into cannabis oils, balm, and foods. Pet. App. 5a.

Diane Monson, a resident of Butte County, California, alleges that she suffers from severe chronic back pain and constant, painful muscle spasms, and that she has been using marijuana to treat her symptoms for more than five years. Pet. App. 5a; J.A. 24-25. In August 2002, federal agents, pursuant to a search warrant, entered Monson's residence and seized six marijuana plants. J.A. 24; see 21 U.S.C. 881(g).

Respondents' suit sought a preliminary injunction to bar the government from enforcing the Controlled Substances Act against them to the extent that it prevents Raich and Monson from possessing, cultivating, and processing marijuana for their purported medical use, and to the extent that it prevents the John Doe respondents from cultivating marijuana and distributing it to Raich for her purported medical use. J.A. 37-39. Respondents urged that the CSA, as applied to their conduct, is unconstitutional and conflicts with what they

characterized as a "doctrine of medical necessity." Pet. App. 6a.

On March 4, 2003, the district court denied the motion for a preliminary injunction, concluding that "the weight of precedent precludes a finding of likelihood of success on the merits." Pet. App. 45a.

3. A divided panel of the court of appeals reversed and remanded. Pet. App. 1a-43a.

a. The court of appeals concluded that respondents "have demonstrated a strong likelihood of success on their claim that, as applied to them, the CSA is an unconstitutional exercise of Congress' Commerce Clause authority." Pet. App. 9a. The court expressed the view that its previous decisions that had uniformly rejected Commerce Clause challenges to the CSA were not controlling, because none of those decisions "involved the use, possession, or cultivation of marijuana for medical purposes." *Id.* at 10a.

In the court's view, the "intrastate, noncommercial cultivation, possession and use of marijuana for personal medical purposes on the advice of a physician" "constitutes a separate and distinct class of activities" that is beyond Congress's power to regulate under the Commerce Clause. Pet. App. 11a (emphasis omitted). The court found that class to be "different in kind from drug trafficking," stating that "this limited use is clearly distinct from the broader illicit drug market—as well as any broader commercial market for medicinal marijuana—insofar as the medicinal marijuana at issue in this case is not intended for, nor does it enter, the stream of commerce." *Ibid.*

The court of appeals also reasoned that "[t]he cultivation, possession, and use of marijuana for medicinal purposes and not for exchange or distribution is not properly characterized as commercial or economic

activity." Pet. App. 14a. On that basis, the court found "not applicable" the "aggregation principle" of *Wickard* v. *Filburn*, 317 U.S. 111 (1942), which, in determining the constitutionality of an Act of Congress under the Commerce Clause, allows for consideration of the cumulative impact on interstate commerce of individual instances of regulated conduct (in *Wickard*, the production of wheat). Pet. App. 15a. The court also rejected the importance of Congress's findings in the CSA regarding the effects of intrastate drug activity on interstate commerce, stating that "[t]he findings are not specific to marijuana, much less intrastate medicinal use of marijuana that is not bought or sold and the use of which is based on the recommendation of a physician," and that in any event such findings should be taken "with a grain of salt." *Id.* at 19a-20a. Finally, the court concluded that the balance of hardships of the parties and public interest factors "tip sharply" in favor of the entry of a preliminary injunction barring enforcement of the CSA. *Id.* at 24a.

b. Judge Beam dissented. Pet. App. 26a-43a. In his view, "[i]t is simply impossible to distinguish the relevant conduct surrounding the cultivation and use of the marijuana crop at issue in this case from the cultivation and use of the wheat crop that affected interstate commerce in *Wickard* v. *Filburn*, [*supra*]." *Id.* at 26a. The dissent explained that the court of appeals' approach ignored "the fungible, economic nature of the substance at issue—marijuana plants—for which there is a well-established and variable interstate market, albeit an illegal one under federal law." *Id.* at 34a; accord *id.* at 34a-35a (Respondents "are growing and/or using a fungible crop which *could* be sold in the marketplace, and which is also being used for medicinal

purposes in place of other drugs which would have to be purchased in the marketplace.").

Judge Beam also concluded that Congress's power to regulate respondents' activities is essential to Congress's ability to regulate "the larger commercial activity" covered by the CSA. Pet. App. 36a. He thus reasoned that, "[i]f Congress cannot reach individual narcotics growers, possessors, and users, its overall statutory scheme will be totally undermined." *Id.* at 38a. Finally, Judge Beam criticized the court's decision to carve out from Congress's general regulatory scheme individual instances of activity based on their ostensibly *de minimis* relation to commerce. *Id.* at 35a-37a.

c. On February 25, 2004, the court of appeals denied the government's petition for rehearing and rehearing en banc. Pet. App. 70a-71a.

4. On May 14, 2004, the district court on remand entered a preliminary injunction enjoining the Attorney General and the Administrator of DEA "from arresting or prosecuting Plaintiffs Angel McClary Raich and Diane Monson, seizing their medical cannabis, forfeiting their property, or seeking civil or administrative sanctions against them with respect to the intrastate, non-commercial cultivation, possession, use, and obtaining without charge of cannabis for personal medical purposes on the advice of a physician and in accordance with state law, and which is not used for distribution, sale, or exchange." Preliminary Injunction Order 1-2 (2004), appeal docketed, No. 04-16296 (9th Cir. June 28, 2004).

SUMMARY OF ARGUMENT

A. Congress has the power under the Commerce Clause, Art. I, § 8, Cl. 3, and the Necessary and Proper Clause, Art. I, § 8, Cl. 18, to regulate local activity that

substantially affects interstate commerce. In *Wickard* v. *Filburn*, 317 U.S. 111 (1942), the Court held that Congress could regulate the production of wheat for consumption rather than sale because that activity affected the regulated interstate market of wheat. *Wickard* establishes that Congress may regulate local activity that is "an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." *United States* v. *Lopez*, 514 U.S. 549, 561 (1995). Congress's determination that local activity with respect to a product substantially affects interstate commerce or could interfere with Congress's objective in regulating the interstate market of that product is entitled to substantial deference. *E.g.*, *Hodel* v. *Indiana*, 452 U.S. 314, 323-324 (1981).

B. The CSA constitutionally regulates the commercial market in marijuana, which is international and interstate in scope. Marijuana is regularly imported into the United States illegally, and domestic trafficking in the drug occurs on a massive scale. Indeed, marijuana traffickers collected an estimated $10.5 billion from American users in 2000 alone. Office of Nat'l Drug Control Policy, Exec. Office of the President, *Marijuana Fact Sheet* 5 (Feb. 2004) (*Marijuana Fact Sheet*). Because marijuana trafficking is quintessentially commercial activity that occurs in interstate and foreign commerce and substantially affects interstate commerce, Congress has the power under the Commerce Clause to regulate all commercial marijuana activity, including commercial possession, manufacture, and distribution that occurs wholly intrastate. *Lopez*, 514 U.S. at 560 ("Where economic activity substantially affects interstate commerce, legislation regulating that activity will be sustained.").

C. The CSA also constitutionally applies to the intrastate manufacture and possession of controlled substances, including marijuana, for personal use, and to the distribution of those substances without charge. Congress has concluded that regulation of all intrastate drug activity "*is essential* to the effective control" of interstate drug trafficking. 21 U.S.C. 801(6) (emphasis added). Congress also has found that controlled substances are readily bought and sold in interstate commerce, 21 U.S.C. 801(3); that local drug possession and distribution swell the interstate drug market, 21 U.S.C. 801(4); and that controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances in the interstate market, 21 U.S.C. 801(5).

Congress accordingly concluded that regulation of intrastate drug activity was a reasonably necessary means to accomplish its comprehensive regulation of the interstate market in controlled substances. Federal regulation of simple drug possession limits the demand for and marketing of the drug. Federal regulation of drug activity that involves personal use or free distribution also permits Congress to control illicit trafficking, as law enforcement officials often cannot readily ascertain whether an unlabeled drug resulted from a sale or will be sold. And excepting drug activity for personal use or free distribution from the sweep of the CSA would discourage the consumption of lawful controlled substances and would undermine Congress's intent to regulate the drug market comprehensively to protect public health and safety. For these reasons, Congress constitutionally has regulated respondents' activities as "an essential part of a larger regulation of economic activity, in which the regulatory scheme could

be undercut unless the intrastate activity were regulated." *Lopez*, 514 U.S. at 561.

D. In holding that the CSA is unconstitutional in its application to respondents' possession and distribution of marijuana, the Ninth Circuit improperly characterized those activities as non-economic and distinct from the more general interstate market of marijuana regulated under the CSA. Respondents' conduct is economic activity that is subject to congressional control because it occurs in, and substantially affects, the marijuana market generally. Home-grown marijuana displaces drugs sold in both the open drug market and the black drug market regulated by the CSA. Respondents' possession and distribution of marijuana also significantly interfere with Congress's objectives in comprehensively regulating the interstate drug market.

The court of appeals also erred in relying on the asserted "medical" nature of respondents' activities. Congress has the power to regulate the interstate market in marijuana as well as activity that substantially affects that market, regardless of the purported use of the drug. Indeed, much of the CSA is addressed to the regulation of substances that (unlike marijuana) have been found by the Secretary of Health and Human Services and the Attorney General to have an accepted medical use. Moreover, the court of appeals relied on policy judgments about the utility and safety of marijuana use that Congress has categorically rejected in the CSA.

ARGUMENT

THE CONTROLLED SUBSTANCES ACT CONSTITUTIONALLY APPLIES TO ALL MANUFACTURE, DISTRIBUTION, AND POSSESSION OF MARIJUANA

It is clear that Congress has the authority under the Commerce Clause to regulate the manufacture, distribution, and possession of marijuana, including when such acts are done in furtherance of purported personal medical use. Congress unquestionably has the power under the Commerce Clause to enact a comprehensive drug statute to regulate and control both interstate and intrastate trafficking in controlled substances, a class of activities that includes commercial manufacture, distribution, and resulting possession of controlled substances.- Congress does not lose its authority if the distribution and possession are not only intrastate, but also allegedly involve marijuana that is home-grown or distributed for free for personal use. Nor does Congress's authority turn on whether the personal use is "medicinal," rather than recreational. Intrastate activities involving marijuana for personal use substantially affect the drug market regulated under the CSA, and exempting such activities would significantly undercut the effectiveness of the comprehensive regulatory regime Congress established to control drug trafficking and abuse. Nor is the purported use of a drug relevant for purposes of determining Congress's power under the Commerce Clause. Indeed, respondents' purported medicinal use of marijuana, a schedule I drug, directly interferes with Congress' comprehensive regulation of the drug and squarely conflicts with Congress's determination that the drug has no accepted medicinal use.

A. Congress May Constitutionally Regulate Activity That Occurs In Or That In The Aggregate Substantially Affects A Regulated Interstate Commercial Market

1. Congress has the power "[t]o regulate Commerce with foreign Nations, and among the several States," Art. I, § 8, Cl. 3, and Congress has corresponding authority under the Necessary and Proper Clause, Art. I, § 8, Cl. 18, to pass legislation that constitutes a reasonable means to effectuate the regulation of interstate commerce. "Congress' commerce authority includes the power to regulate those activities having a substantial relation to interstate commerce, . . . *i.e.*, those activities that substantially affect interstate commerce." *United States* v. *Morrison*, 529 U.S. 598, 609 (2000) (quoting *United States* v. *Lopez*, 514 U.S. 549, 558 (1995)). Thus, it has long been established that "[t]he power of Congress over interstate commerce is not confined to the regulation of commerce among the states. It extends to those activities intrastate which so affect interstate commerce or the exercise of the power of Congress over it as to make regulation of them appropriate means to the attainment of a legitimate end, the exercise of the granted power of Congress to regulate interstate commerce." *United States* v. *Darby*, 312 U.S. 100, 118 (1941); accord *Wickard*, 317 U.S. at 124 (quoting *United States* v. *Wrightwood Dairy Co.*, 315 U.S. 110, 119 (1942)); see *NLRB* v. *Jones & Laughlin Steel Corp.*, 301 U.S. 1, 36-37 (1937) ("[T]he power to regulate commerce is the power to enact 'all appropriate legislation' for 'its protection and advancement.'") (citing *The Daniel Ball*, 77 U.S. (10 Wall.) 557, 564 (1870)).

This Court's precedents also confirm that "where *a general regulatory statute bears a substantial relation to commerce*, the *de minimis* character of individual instances arising under that statute is of no consequence." *Lopez*, 514 U.S. at 558 (quoting *Maryland* v. *Wirtz*, 392 U.S. 183, 197 n.27 (1968)); accord *Perez* v. *United States*, 402 U.S. 146, 154 (1971) ("Where the *class of activities* is regulated and that class is within the reach of federal power, the courts have no power 'to excise, as trivial, individual instances' of the class.") (quoting *Wirtz*, 392 U.S. at 193).

That principle is illustrated by *Wickard* v. *Filburn*, *supra*, in which the Court upheld the federal regulation of wheat, which was grown and consumed on a family farm, as part of a comprehensive program to control the volume and price of wheat moving in interstate and foreign commerce. The Court reached that result even though the wheat was not "sold or intended to be sold," 317 U.S. at 119; the production of wheat "may not be regarded as commerce," *id.* at 125, and the regulated individual's own activity "may be trivial by itself," *id.* at 127. The Court explained that local activity may, "whatever its nature, be regulated by Congress if it exerts a substantial effect on interstate commerce." *Id.* at 125. In *Wickard* itself, the Court held that Congress's regulation of the purely local activity of growing wheat even for consumption on the farm was reasonably necessary to achieve Congress's broader regulation of the supply, demand, and prices in the interstate wheat market, which is indisputably subject to its power under the Commerce Clause. *Id.* at 127-129.

Wickard thus establishes that Congress may regulate intrastate activity which itself may not be overtly commercial in nature—in the sense that it does not directly involve an exchange for valuable consideration—if regulation of the activity is reasonably neces-

sary to achieve the effective regulation of a market that is interstate in nature. This Court explained in *Lopez*, *supra*, that the production of wheat that Congress chose to regulate in *Wickard* was subject to federal regulation even though the specific wheat at issue was produced for personal use and the regulated activity "may not be regarded as commerce." *Lopez*, 514 U.S. at 556 (quoting *Wickard*, 317 U.S. at 125). In distinguishing the statute in *Wickard* from the Gun-Free School Zones Act of 1990, 18 U.S.C. 922(q), at issue in *Lopez*, the Court explained that "*Wickard* * * * involved economic activity in a way that the possession of a gun in a school zone does not." *Lopez*, 514 U.S. at 560. The Court further explained that, unlike the statute in *Wickard*, Section 922(q) was not "an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." *Lopez*, 514 U.S. at 561; see also *Morrison*, 529 U.S. at 610.

2. In determining whether a federal statute may be sustained as a proper exercise of Congress's power to regulate interstate commerce, courts apply a "rational basis" standard that reflects broad deference to legislative judgments regarding whether the intrastate activity at issue substantially affects interstate commerce and whether regulation of the activity is reasonably necessary to achieve Congress's purposes. See *Lopez*, 514 U.S. at 557; *Wirtz*, 392 U.S. at 198. "A court may invalidate legislation enacted under the Commerce Clause only if it is clear that there is no rational basis for a congressional finding that the regulated activity affects interstate commerce, or that there is no reasonable connection between the regulatory means selected and the asserted ends." *Hodel* v. *Indiana*, 452 U.S. at 323-324; see *e.g.*, *Jinks* v. *Richland County*, 538

U.S. 456, 461-464 (2003); *Preseault* v. *ICC*, 494 U.S. 1, 17 (1990); *M'Culloch* v. *Maryland*, 17 U.S. (4 Wheat.) 316, 419 (1819); accord *Sabri* v. *United States*, 124 S. Ct. 1941, 1946 (2004) (Spending Clause).

B. The CSA Comprehensively Regulates The Market In Controlled Substances

1. Congress passed the CSA "to deal in a comprehensive fashion with the growing menace of drug abuse in the United States * * * through providing more effective means for law enforcement aspects of drug abuse prevention and control." H.R. Rep. No. 1444, *supra*, Pt. 1, at 1; accord S. Rep. No. 613, 91st Cong., 1st Sess. 3 (1969) ("[T]he overall purpose of the bill is to improve the administration and regulation of the manufacture, importation and exportation of the controlled dangerous substances covered under its provisions, so that the widespread diversion presently occurring can be halted."). In furtherance of its central purposes, the CSA comprehensively bans *all* manufacture, distribution, and possession of any scheduled drug unless explicitly authorized by the Act. 21 U.S.C. 841(a)(1), 844(a). That is why marijuana, like all other listed drugs, is a "controlled" substance under the CSA. The Act thus establishes "a 'closed' system of drug distribution" for all controlled substances by "provid[ing] for control * * * of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and [by] mak[ing] transactions outside the legitimate distribution chain illegal." H.R. Rep. No. 1444, *supra*, Pt. 1, at 3, 6. Congress thereby sought to "significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug

industry with a unified approach to narcotic and dangerous drug control." *Id.* at 6; see *Moore*, 423 U.S. at 135, 141.

2. The CSA obviously includes within its comprehensive scope quintessentially commercial activity—the manufacture and distribution of drugs for consideration, and the possession of drugs in connection with or as a result of such transactions—that in large part takes place *in* interstate and foreign commerce and that categorically *affects* interstate commerce. Congress in the CSA found that "[a] major portion of the traffic in controlled substances flows through interstate and foreign commerce." 21 U.S.C. 801(3). Congress was also aware that the national drug abuse problem sought to be addressed by the CSA stemmed from "the illicit traffic in drugs which is both international and interstate in scope." S. Rep. No. 613, *supra*, at 3. Congress accordingly determined that "Federal * * * regulation and control [of controlled substances] is required to help manage the drug abuse problem and the criminal traffic in drugs on the international, national, and State levels." *Id.* at 4.

Those judgments were well founded and remain accurate today. "The illegal drug market in the United States is one of the most profitable in the world." DEA, *Drug Trafficking in the United States* 1 (Sept. 2001) (*Drug Trafficking*) <http://www.usdoj.gov/dea/concern/drug_trafficking.html>. A diverse and sophisticated group of international and domestic traffickers engage in the illicit commercial manufacture, distribution, and possession of drugs in this country. For instance, "[c]riminal groups operating from South America smuggle cocaine and heroin into the United States"; "criminal groups operating from neighboring Mexico smuggle cocaine, heroin, methamphetamine, amphetamine, and marijuana into the United States"; and "Israeli and Russian drug trafficking syndicates and Western Europe-based drug traffickers are the principal traffickers of MDMA [ecstasy] worldwide." *Ibid.*; accord S. Rep. No. 613, *supra*, at 3-4 ("There is an unknown quantity of the nonmedical and nonprescription drugs (heroin, cocaine, marihuana) being continuously smuggled into this country."). In addition to the criminal groups based abroad, "domestic organizations cultivate, produce, manufacture, or distribute illegal drugs such as marijuana, methamphetamine, phencylidine (PCP), and lysergic acid diethyamide(LSD)." *Drug Trafficking* 1.

The interstate market for marijuana that Congress regulates under the CSA is well-established and substantial. At the time Congress passed the CSA, marijuana was "the most popular drug of abuse," and marijuana offenses had accounted for "the bulk of drug arrests throughout the Nation." S. Rep. No. 613, *supra*, at 2, 3. Even today, despite the federal prohibitions on marijuana, "[t]he indoor and outdoor cultivation in most regions of the country, as well as the presence of marijuana smuggled into the United States from foreign sources, contributes to the pervasiveness of the drug." Drug Availability Steering Committee, *Drug Availability in the United States* 103 (Dec. 2002) (*Drug Availability*) <http://www.whitehousedrugpolicy.gov/publications/pdf/drugavailability.pdf>. Indeed, "U.S. marijuana users spent approximately $10.5 billion on marijuana in 2000." *Marijuana Fact Sheet* 5. The illicit marijuana market is also well-defined according to geographic areas and the particular type of marijuana being sold. National Drug Intelligence Center, *National Drug Threat Assessment 2004*, at 3 (Apr. 2004) (*National Drug Threat Assessment*) ("Marijuana

prices, an indication of marijuana's steady availability, have been stable for years, although prices range considerably from market to market depending on the type and potency available, quantity purchased, purchase frequency, buyer-seller relationship, and proximity to source.") <http://www.usdoj.gov/ndic/pubs8/8731/marijuana.htm>; *Illicit Drug Prices July 2003-December 2003*, Narcotics Digest Weekly, Dec. 16, 2003, at 1 & Table 4, at 19-25 (listing, for all 50 States and District of Columbia, wholesale, midlevel, and retail prices for "BC Bud" (*i.e.*, high-potency Canadian), commercial grade, domestic, hydroponic, locally produced, imported, Mexico-produced, and sinsemilla marijuana). And marijuana is readily and commonly transported across state lines. *E.g.*, *National Drug Threat Assessment* 13-14 ("Throughout the United States a wide range of organizations, groups, gangs, and independent dealers transport—and distribute—marijuana."). Congress's commerce power accordingly extends to the comprehensive regulation of all commercial marijuana activity throughout the Nation.

C. The CSA Constitutionally Includes Wholly Intrastate Manufacture, Free Distribution, And Possession Of Marijuana

Respondents' intrastate drug distribution and use are subject to congressional regulation because Congress rationally determined that such activities as a class substantially affect the marijuana market as a whole. Regulation of such activities also is a necessary and proper means to effectuate Congress's comprehensive regulation of the interstate market for marijuana. Indeed, the CSA is a compelling instance in which Congress's power "extends to those activities intrastate which so affect interstate commerce or the

exercise of the power of Congress over it as to make regulation of them appropriate means to the attainment of a legitimate end." *Darby*, 312 U.S. at 118.

Congress manifestly has the authority under the Commerce Clause to regulate the *commercial* manufacture, distribution, and possession of any controlled substance, even if such activity takes place entirely *intrastate*. *Lopez*, 514 U.S. at 559 ("[W]e have upheld a wide variety of congressional Acts regulating intrastate economic activity where we have concluded that the activity substantially affected interstate commerce."); see *e.g.*, *United States* v. *Wrightwood Dairy Co.*, 315 U.S. 110, 118-121 (1942); *Darby*, 312 U.S. at 118-119. This Court's decisions thus firmly establish that Congress may ban a commercial activity, whether it occurs in interstate or intrastate commerce, when the commercial activity, in the aggregate, affects interstate commerce. See, *e.g.*, *Perez*, *supra* (loan sharking); *Minor* v. *United States*, 396 U.S. 87, 98 (1969) (observing that "a flat ban on certain sales [of narcotics] is sustainable under the powers granted Congress in Art. I, § 8.").

Likewise, the fact that respondents' conduct is not only intrastate, but also purportedly limited to distribution and possession for personal use, does not eliminate Congress's authority. The constitutionality of the CSA as applied to drug distribution and possession for personal use follows from the Court's unanimous decision in *Wickard*, and from the Court's reaffirmation of *Wickard* in *Lopez*. See *Brzonkala* v. *Virginia Polytechnic Inst. & State Univ.*, 169 F.3d 820, 836 n.7 (4th Cir. 1999) (en banc), aff'd *sub nom. United States* v. *Morrison*, 529 U.S. 598 (2000). The growing and processing of marijuana and its resulting possession for personal use "involve[] economic activity"—the production of a fungible commodity for which there is an

established market—in the same way as the growing of wheat for consumption does, and "in a way that possession of a gun in school zone does not." *Lopez*, 514 U.S. at 560. Judge Luttig made that very point in distinguishing the regulation of marijuana for personal use under the CSA from the provision of the Violence Against Women Act struck down in *Morrison*, *supra*, observing that, "[l]ike the production of home-grown wheat, the manufacture of marijuana for personal use is an economic activity in a general sense." *Brzonkala*, 169 F.3d at 836 n.7. As Judge Luttig further explained, in both situations, the activity is regulated "pursuant to a comprehensive statutory scheme" regulating the trade of a product "which is assuredly both commercial and interstate." *Ibid.* "Thus, like the regulation of home-grown wheat, the prohibition of home-grown marijuana is 'an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated.'" *Ibid.* (quoting *Lopez*, 514 U.S. at 561); accord *United States* v. *Lopez*, 2 F.3d 1342, 1367 n.51 (5th Cir. 1993) ("The [CSA's] possession proscription [is] a necessary means to regulate the interstate commercial trafficking in narcotics."), aff'd, 514 U.S. 549 (1995). As explained below, those conclusions are amply supported by Congress's findings when it enacted the CSA and the nature of the problem that the CSA addresses.

1. Congress reasonably found that intrastate drug manufacture, distribution, and possession substantially affect interstate drug commerce and that federal regulation of that intrastate activity is essential to achieve Congress's regulation of drug commerce

a. Section 801 of the CSA sets forth "the principal reasons" why Congress deemed it "necessary to make

the controls of [the CSA] applicable to all controlled substances regardless of whether they or their components have ever been outside the State in which they are found." H.R. Rep. No. 1444, *supra*, Pt. 1, at 29. Congress concluded that, although the manufacture, local distribution, and possession of controlled substances "are not an integral part of the interstate or foreign flow" of drugs, those activities are nonetheless "incidents" of the interstate and foreign drug traffic that "have a substantial and direct effect upon interstate commerce." 21 U.S.C. 801(3). Significantly, Congress did *not* rely on the aggregate effects of illicit local drug activity on the *national economy*. See *Morrison*, 529 U.S. at 615-619. Rather, Congress viewed intrastate drug activity as significantly affecting the interstate *market* for the drugs that are regulated under the statute. Specifically, Congress found that "[l]ocal distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances" (21 U.S.C. 801(4)); that "after manufacture, many controlled substances are transported in interstate commerce" (21 U.S.C. 801(3)(A)); that "controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution," (21 U.S.C. 801(3)(B)); and that "controlled substances possessed commonly flow through interstate commerce immediately prior to such possession," 21 U.S.C. 801(3)(C); accord H.R. Rep. No. 1444, *supra*, Pt. 1, at 29. For those reasons, Congress concluded that "*[f]ederal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.*" 21 U.S.C. 801(6) (emphasis added).

Those findings fully support Congress's conclusions that the local manufacture, distribution, and possession

of drugs, including marijuana, are significantly linked to the commerce in drugs regulated under the statute and that comprehensive regulation of that local activity is essential to effectuate control of the interstate drug market.[2] Local manufacture, distribution, and use of controlled substances—and their possession for those purposes—directly increase the supply of those substances, which in turn increases demand for these substances, which leads to further increases in supply and the marketing to users, thus "swelling" the traffic in the drug. 21 U.S.C. 801(4). "Laws criminalizing the possession of a good decrease the demand for that good. This decreased demand results in a decrease of supply as production becomes less profitable and therefore less attractive." *United States* v. *Adams*, 343 F.3d 1024, 1033 (9th Cir. 2003), cert. denied, 124 S. Ct. 2871 (2004). A criminal ban on possession also serves as "a marketing impediment to those inclined to violate the prohibition on sale." *United States* v. *Franklyn*, 157 F.3d 90, 96 (2d Cir. 1998), cert. denied, 525 U.S. 1112 (1999); cf. *Osborne* v. *Ohio*, 495 U.S. 103, 109-110 (1990) ("It is

[2] The Ninth Circuit concluded that the Court's decision in "*Morrison* counsels courts to take congressional findings with a grain of salt." Pet. App. 20a. That is not correct. *Morrison* held that Congress lacked the power under the Commerce Clause to regulate gender-motivated violence despite Congress's findings that such violence had significant effects on the national economy and interstate commerce. 529 U.S. at 615-619. The Court did not, however, cast doubt on its earlier decisions holding that Congress's findings are entitled to deference. Rather, the Court assumed the rationality of Congress's findings, but concluded, as matter of constitutional principle, that Congress's justification was too broad because it would permit Congress to regulate all non-economic crimes in areas of traditional state regulation, thereby blurring the "distinction between what is truly national and what is truly local." *Id.* at 617-618.

* * * surely reasonable for the State to conclude that it will decrease the production of child pornography if it penalizes those who possess and view the product, thereby decreasing demand.").

If Congress lacked the power to regulate either the intrastate production, distribution, and possession of marijuana generally, or the production, distribution, and possession of marijuana for personal use, the market effects on the demand and supply of marijuana would likely be enormous. "[B]oth law enforcement and public health agencies consistently identify marijuana as the most commonly used illicit drug in the country." *National Drug Threat Assessment* 1. "The demand for marijuana far exceeds that for any other illicit drug and the size of the American user population equates to steady profits for traffickers." *Drug Availability* 103. The risk that both the supply and demand could dramatically increase were home-grown marijuana beyond the reach of federal law is obvious. Users of home-grown marijuana and those who distribute it for free (such as the John Doe respondents) may ultimately purchase marijuana in the black market, if, for example, their production efforts fail or fall short. Indeed, respondents, like many other claimed medical marijuana users, view marijuana consumption as a *medical necessity*. Br. in Opp. 26-29; Pet. App. 84a-85a; J.A. 32-33 (Complaint); *Oakland Cannabis*, *supra*.

The "home-grown" manufacturing, free distribution, and possession of controlled substances, whether for recreational or purported medicinal purposes, also pose an appreciable risk of diversion to others for further drug use or distribution, a result that further swells the illicit market. Local users may ultimately sell or divert the drug to others (for instance, should their production yield exceed their purported needs or should additional

funds be required to finance their drug production or other activities). The risk of diversion is particularly acute under the regime contemplated by the Ninth Circuit, in which persons, such as the John Doe respondents, may manufacture and distribute marijuana to others without charge. Such persons would have an available supply of home-grown marijuana to sell to meet their own financial needs, and they are likely to have no ready means to ensure that the recipients of the marijuana to whom they distribute it for free will not in turn put the drug into the stream of commerce. See Pet. App. 34a (Beam, J., dissenting) (Respondents "are growing and/ or using a fungible crop which *could* be sold in the marketplace.").

Finally, the fact that the purported personal use is for medical, rather than recreational, use does nothing to strengthen respondents' Commerce Clause challenge. In the first place, the entirety of the CSA involves the regulation of drugs, most of which, *i.e.*, those in schedules II through V, have some accepted medical use. See pp. 39-41, *infra*. In addition, local illicit drug use for purported medicinal purposes significantly affects the drug commerce subject to Congress's regulation by inducing the "medicinal" user to refrain from consuming lawful drugs, Pet. App. 34a-35a, 36a (Beam, J., dissenting), or by decreasing the incentives for research and development into new legitimate drugs. Cf. *United States* v. *Rutherford*, 442 U.S. 544, 556 (1979) ("[I]f an individual suffering from a potentially fatal disease rejects conventional therapy in favor of a drug with no demonstrable curative properties, the consequences can be irreversible."). For instance, one method of delivery of cannabinoids currently available is Marinol®, which contains a synthetic form of tetrahdyrocannabinol (THC) in pill form. Marinol® has

been approved by the FDA for the treatment of nausea and vomiting associated with cancer chemotherapy and for the treatment of anorexia associated with weight loss in AIDS patients. 64 Fed. Reg. 35,928 (1999). On July 2, 1999, DEA transferred Marinol® from schedule II to schedule III under the CSA, thereby lessening the regulatory restrictions on its use. *Id.* at 35,929. Indeed, respondents Raich and Monson were users of many lawful prescription drugs that are controlled under the CSA, including Marinol®, before they turned to marijuana. J.A. 49-50, 53, 56. Although particular individuals such as respondents may find that lawful drugs such as Marinol® are ineffective or cause serious side-effects, Congress rationlly and constitutionally concluded that the public should use only those drugs that the FDA has approved as safe and effective for some medical use—and, if listed under the CSA because of their potential for abuse and dependency, subject to the CSA's stringent controls that guard against abuse and diversion.

For the foregoing reasons, Congress's unquestionable power to eradicate drug trafficking and distribution also includes the power to ban all production, possession, and use that feeds the illicit drug market. Indeed, courts have generally upheld laws that ban the intrastate possession or manufacture of a commodity as a reasonably necessary means of regulating commerce in the commodity. See, *e.g.*, *United States* v. *Rybar*, 103 F.3d 273, 283 (3d Cir. 1996) (federal statute validly "targets the possession of machine guns as a demand-side measure to lessen the stimulus that prospective acquisition would have on the commerce in machine guns"), cert. denied, 522 U.S. 807 (1997); *Navegar, Inc.* v. *United States*, 192 F.3d 1050, 1058 (D.C. Cir. 1999) (statutory ban on possession of assault weapons "is a

measure intended to reduce the demand"), cert. denied, 531 U.S. 816 (2000); *United States* v. *Cardoza*, 129 F.3d 6, 12 (1st Cir. 1997) ("[G]iven Congress' express purpose [to stop commerce in handguns by juveniles], its decision to punish both the supply (sale or transfer) and demand (possession) sides of the market is a means reasonably calculated to achieve its end. * * * * * The two prohibitions go hand in hand with one another. Invalidation of one half of the equation would likely have deleterious effects on the efficacy of the legislation.").[3]

b. This Court's cases also recognize that effective national approaches may require the regulation of purely local activity to prevent the circumvention of federal rules and to facilitate a comprehensive system of regulation. See, *e.g.*, *Wickard*, *supra*. In the CSA, Congress rationally addressed all activity involving controlled substances in light of the substantial difficul-

[3] Congress has passed many laws banning the intrastate possession of a product in order to eliminate an entire market for the commodity. *E.g.*, 16 U.S.C. 668(a) (bald and golden eagles); 18 U.S.C. 175(a) (biological weapons), 18 U.S.C. 831(a) (nuclear material), 18 U.S.C. 842(n)(1) (certain plastic explosives); 18 U.S.C. 922(o)(1) (machinegun); 18 U.S.C. 922(v)(1) (semiautomatic assault weapons); 18 U.S.C. 922(x)(1) (handguns by juveniles); 18 U.S.C. 2342(a) (contraband cigarettes); 18 U.S.C. 2252(a)(4)(B) (child pornography produced with materials shipped in interstate commerce); cf. *United States* v. *Bass*, 404 U.S. 336, 339 n.4 (1971) (declining to reach the question "whether, upon appropriate findings, Congress can constitutionally ban the 'mere possession' of firearms"). Shortly before its decision in this case, the Ninth Circuit issued two other decisions holding that Congress lacked power under the Commerce Clause to regulate possession of such products. *United States* v. *Stewart*, 348 F.3d 1132, 1134-1140 (2003) (homemade machinegun); *United States* v. *McCoy*, 323 F.3d 1114, 1117-1130 (2003) (home-produced child pornography).

ties that would be encountered by law enforcement officials if proof were required as to the origin of a drug or the commercial intentions of the person in whose possession the drug was discovered. As Congress found, many drugs produced are thereafter sold (21 U.S.C. 801(3)(A)), and many drugs possessed are the result of a previous sale (21 U.S.C. 801(3)(C)). Congress also found, however, that, given the fungible nature of drugs, "[c]ontrolled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate," and thus that "it is not feasible to distinguish" between such substances "in terms of controls." 21 U.S.C. 801(5); accord S. Rep. No. 613, *supra*, at 4.[4]

That finding comports with common sense, and fully justifies the regulation of intrastate as well as interstate activities. See, *e.g.*, *Darby*, 312 U.S. at 117-118; *Currin* v. *Wallace*, 306 U.S. 1, 11 (1939); compare *Sabri*, 124 S. Ct. at 1946. It often would be impossible to ascertain in any given case whether an illicit, unlabeled drug, such as marijuana, has either been purchased or

[4] Likewise, shortly before the passage of the CSA, Congress passed the Drug Abuse Control Amendments of 1965, which amended the Food, Drug and Cosmetic Act, to establish controls for depressant and stimulant drugs. Pub. L. No. 89-74, 79 Stat. 226. Congress therein found that "in order to make regulation and protection of interstate commerce in such drugs effective, regulation of intrastate commerce is also necessary because, among other things, such drugs, when held for illicit sale, often do not bear labeling showing their place of origin and because in the form in which they are so held or in which they are consumed a determination of their place of origin is often extremely difficult or impossible." § 2, 79 Stat. 227. In enacting the CSA, Congress reasonably drew upon its earlier experience in attempting to control the interstate drug market. See *Fullilove* v. *Klutznick*, 448 U.S. 448, 503 (1980) (Powell, J., concurring).

is intended to be offered for sale. That is true not only of the processed marijuana smoked by respondents Raich and Monson, but also of the other home-made marijuana products such as "cannabis oils, balm, and foods" that Raich processes and consumes. Pet. App. 5a. There accordingly would be difficult, if not impossible, questions of proof if the government were required to demonstrate that a given quantity of marijuana that a person possessed, manufactured, or distributed to others without charge had previously entered, or would enter, into the stream of monetary commerce. Indeed, much of the marijuana obtained by users "for free" from friends or acquaintances was, at some earlier point, presumably purchased in a commercial transaction. Cf. *Marijuana Fact Sheet* 4 ("About 79% of marijuana users who bought the drug and 81.8% who obtained the drug for free got it from a friend."). But *proof* of that prior commercial chain of custody would be exceedingly difficult. Those difficulties of proof would be compounded by the fact that commercial production, distribution, and related possession of marijuana take place in an *illicit* market. The illicit nature of the market requires that the activity be undertaken in a clandestine manner to evade detection by law enforcement officers, see, *e.g.*, *Drug Trafficking* 10, *National Drug Threat Assessment* 8-12, and is wholly inconsistent with the kind of regulation and labeling that would be required to prove (or disprove) that certain drugs flowed in interstate or foreign commerce or were not for medicinal use.

Moreover, because the FDA has never approved marijuana as safe and effective for any medicinal use, and Congress has determined in the CSA that marijuana has no acceptable medical uses, 21 U.S.C. 812(b)(1)(B), there are no federal standards by which to

judge how much marijuana appropriately could be possessed, home-grown, or distributed for personal "medicinal" use. Not surprisingly, marijuana users consume the drug "at varying rates and in unlike quantities," and the drug itself has widely "varying potency." *Drug Availability* 138. Thus, it would often be difficult to prove whether relatively small quantities of marijuana were being held, produced, or distributed for commercial, recreational or medicinal use. *E.g.*, *People* v. *Mower*, 49 P.3d 1067, 1072, 1084 (Cal. 2002) (holding that a jury question existed whether possession of 31 marijuana plants was for personal medicinal use under Cal. Health & Safety Code § 11362.5, where defense presented evidence that plants would yield harvest of five pounds and prosecution presented evidence that plants would yield between 31 and 62 pounds).

The Ninth Circuit dismissed these law enforcement concerns, observing that "the marijuana in the instant case never entered into and was never intended for interstate or foreign commerce." Pet. App. 21a n.7. The court, however, failed to explain how, under the court's decision, federal law enforcement officials would enforce the CSA as to persons consuming, possessing, growing, or distributing marijuana where specific proof of a commercial transaction or purpose is lacking. In those situations, the CSA could not be enforced even though Congress specifically found that controlled substances typically have or will enter the stream of commerce. 21 U.S.C. 801(3). Thus, Congress would lack the power to provide for the effective enforcement of the CSA with respect to a large category of individuals who are engaging in commercial activity clearly subject to congressional regulation. Given that there are an estimated 25.8 million current users of marijuana in the United States—even though the manufacture, distribu-

tion, and possession of marijuana are categorically *illegal* under federal law, *Marijuana Fact Sheet* 1—the law enforcement problems created by exempting non-commercial and intrastate marijuana activities from the CSA's reach could well be staggering.

A ban on all possession is accordingly essential to permit "law enforcement to effectively regulate the manufacture and transfers where the product comes to rest, in the possession of the receiver." *Navegar, Inc.*, 192 F.3d at 1059. As the Fifth Circuit has observed in rejecting a challenge to the statutory prohibition of possession of child pornography, a market "is pushed by supply and demand, whether manifested in swaps or purchase and sale," and "where the product is fungible, such that it is difficult if not impossible to trace, Congress can prohibit local possession in an effort to regulate product supply and demand and thereby halt interstate trade." *United States* v. *Kallestad*, 236 F.3d 225, 231 (2000).

2. Federally unregulated local manufacture, distribution, and possession of controlled substances would substantially undercut Congress's closed system of distribution of those dangerous drugs

The intrastate manufacture, possession, and free distribution of controlled substances would significantly interfere with Congress's objectives under the CSA to establish a national, comprehensive, uniform—and closed—statutory scheme to control the market in controlled substances in order to prevent the abuse and diversion of those substances. As discussed above (at 23-32), the unregulated intrastate manufacturing, possession, and distribution of a drug would contribute to the illicit trafficking in and marketing of the drug, would increase the likelihood that the drug would be

diverted and sold for illegitimate uses, and would prevent effective enforcement of the interstate ban on drug trafficking. The CSA's closed system of distribution was designed to address those serious problems, while at the same time providing a means for the production and distribution under the strict controls in the CSA itself of those controlled substances that (unlike marijuana) have been found to have accepted and legitimate medical uses.

The adverse effect of the court of appeals' decision on the administration and enforcement of the CSA is readily illustrated as applied to the manufacture, distribution, and possession of drugs listed in schedules II through V (such as methadone, codeine and other opioids), which may be dispensed and prescribed for medical use. 21 U.S.C. 812(b)(2)(B), (3)(B), (4)(B) and (5)(B). Although such drugs have an accepted medical use in treatment, they nonetheless are subject to abuse and resulting dependence, with attendant adverse consequences to public health and safety. 21 U.S.C. 812(b)(2)(A) and (C), (3)(A) and (C), (4)(A) and (C), and (5)(A) and (C). The CSA accordingly requires manufacturers, physicians, pharmacies, and other legitimate handlers of such drugs to comply with stringent statutory and regulatory provisions that mandate registration with the DEA, require compliance with specific production quotas, establish security controls to guard against the theft or diversion of drugs, impose record-keeping and reporting obligations, and permit the drug to be distributed and dispensed only pursuant to specific order-form and prescription requirements. 21 U.S.C. 821-829; 21 C.F.R. Pts. 1301-1306.

Were Congress to lack the power under the Commerce Clause to apply the CSA to the intrastate manufacture, free distribution, and possession of controlled

substances on schedules II through V, persons operating intrastate could function essentially as unregulated and unsupervised drug manufacturers and pharmacies without being subject to *any* of the federal controls Congress put in place under the CSA. That state of affairs would manifestly undermine the CSA's purposes to establish a comprehensive and unified approach to "dangerous drug control" and to guard against the risks of drug abuse and the diversion of controlled substances from "legitimate channels into the illicit market." H.R. Rep. No. 1444, *supra*, Pt. 1, at 6. Such a regime would also cause the precise threats to public health and safety that Congress sought to avert in passing the CSA. See 21 U.S.C. 801 (finding that "[t]he illegal * * * manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.").

The threat to the comprehensive nature of the CSA from an intrastate, personal use, or free distribution exception would be greater still for *a schedule I drug*, like marijuana, which Congress has found has *no* accepted medical use and may not be manufactured, distributed, or possessed under *any* circumstances, except as part of a strictly controlled research project. 21 U.S.C. 812(b), 823(f). Congress's efforts to control any trafficking in marijuana would be significantly undermined were Congress to lack the power to prevent the manufacture, free distribution, and related possession of marijuana from swelling the market, and thereby to make effective the exercise of its undeniable power to eradicate marijuana trafficking. Congress's purpose to prevent the social harms stemming from drug abuse similarly would be defeated were Congress to lack the power to prevent such activities. As Judge Beam concluded, "[i]f Congress cannot reach individual [marijuana] growers, possessors, and users, its overall statutory scheme will be totally undermined." Pet. App. 38a. This is clearly a situation in which the intrastate activities at issue not only "affect interstate commerce," but also "the exercise of Congress's power over it." *Darby*, 312 U.S. at 118. The regulation of such activities is, therefore, a necessary and proper means of ensuring the full accomplishment of the purposes of the CSA and the integrity of its closed system of distribution. See, *e.g.*, *Sabri*, 124 S. Ct. at 1946-1947; *Jinks*, 538 U.S. at 461-464.

D. The Ninth Circuit's Reliance On Respondents' Purported Medical Use Of Marijuana Is Seriously Flawed

The court of appeals apparently accepted the proposition that the CSA constitutionally applies to a broad class of activities that includes the commercial manufacture, distribution, and possession of controlled substances, including marijuana, whether these activities occur interstate or intrastate. Pet. App. 10a-11a. The court held, however, that the CSA could not constitutionally be applied to what it characterized as a "*separate and distinct class of activities*: the intrastate, noncommercial cultivation and possession of cannabis for personal medical purposes as recommended by a patient's physician pursuant to valid California state law," *id.* at 11a, because the court of appeals did not perceive that class to involve economic activity or to have a substantial effect on interstate commerce, *id.* at 11a-12a, 16a-17a.

The court's reasoning rested on two equally mistaken premises. First, the court improperly excised a subclass of activities that cannot be divorced from the

general class of activities regulated by the CSA. Second, the court erroneously concluded that factors it believed to be unique to the assertedly medical use of marijuana as approved by a physician render Congress powerless to regulate the manufacture, free distribution, and possession of marijuana under the CSA when such activities occur for purported medical purposes.

1. Respondents are engaged in economic activity

The court's reliance on the non-commercial nature of respondents' conduct ignores the fact that the sort of drug activities in which respondents engage were reasonably determined by Congress to be part of the overall class of activities covered by the CSA—the manufacture, distribution, and possession of controlled substances—that unquestionably "involve[s] economic activity" and substantially affects commerce. *Lopez*, 514 U.S. at 560. Because the CSA is a "*general regulatory statute*" that "*bears a substantial relation to commerce*, the *de minimis* character of individual instances arising under *that statute* is of no consequence." *Id.* at 558 (quoting *Wirtz*, 392 U.S. at 197 n.27) (last emphasis added). As the Second Circuit has explained in upholding the CSA as applied to the manufacture of marijuana without the intent to distribute it, "[t]he nexus to interstate commerce * * * is determined by the class of activities regulated by the statute as a whole, not by the simple act for which an individual defendant is convicted." *Proyect* v. *United States*, 101 F.3d 11, 13 (2d Cir. 1996); see *United States* v. *Davis*, 288 F.3d 359, 362 (8th Cir.) (sustaining application of CSA restriction on possession to a defendant's home manufacture of methamphetamine because the conduct constituted part of the "economic endeavor" compre-

hensively regulated by the statute), cert. denied, 537 U.S. 822 (2002); accord *United States* v. *Leshuk*, 65 F.3d 1105, 1112 (4th Cir. 1995). The Ninth Circuit accordingly erred in seizing on whether respondents' activities, in isolation, were non-commercial or had interstate effects, without ever considering whether Congress reasonably included respondents' activities as part of the overall class of drug activities regulated by the CSA in order to establish a comprehensive scheme of regulation of the market in controlled substances.

Moreover, as noted above (see pp. 21-22, *supra*) respondents' manufacturing, distribution, and possession activities themselves "involved economic activity" (*Lopez*, 514 U.S. at 560) to at least the same extent as Roscoe Filburn's home-grown production of wheat in *Wickard*. In both cases, the regulated individuals are producing a fungible commodity for which there is an established market and are doing so for their own use when they would otherwise be participants in a regulated market. Indeed, the Doe respondents are producing and distributing the commodity for *others*, but claim to distribute it free of charge. In *Wickard*, Filburn would have purchased his wheat in the open market to meet his needs. Likewise, in this case, persons such as respondents would presumably either purchase FDA-approved (and if listed, CSA-controlled) prescription drugs in the open market or purchase marijuana in the black market. Indeed, respondent Monson testified in this case that as a result of the DEA's seizure of her "medicinal [marijuana] plants," "I must now find a way to get my medicine *from another source*." J.A. 59 (emphasis added). Similarly, respondent Raich testified that she has previously obtained her marijuana from the Oakland Cannabis Buyers' Cooperative, a commercial distributor of marijuana, and

she also testified that after federal agents shut down that cooperative, "I was forced to obtain my medication *on the street*." J.A. 87 (emphasis added). More broadly, the prevailing conditions in the commercial market for wheat or marijuana influence the extent to which individuals self-produce or buy on the open market, and the activities of these individuals in turn affect the market. See *Lopez*, 514 U.S. at 560-561 (quoting *Wickard*, 317 U.S. at 128).

To be sure, in *Wickard*, the home-grown production competed with wheat in a *lawful* market that Congress sought to protect and stabilize, whereas marijuana is an illicit substance (except in the context of strictly controlled research projects) and therefore is distributed in an *unlawful* market. But there is nothing in the Court's Commerce Clause jurisprudence that suggests that Congress's power is weaker when a regulated product is particularly harmful and therefore illicit. The salient point is that for both the wheat in *Wickard* and the marijuana here, the commodity at issue is subject to a comprehensive scheme of regulation clearly within Congress's commerce power, and the activities of those who produce, possess, or distribute the commodity for personal use have economic impacts on the market in such a way as to interfere with Congress's attempt to regulate it.

The Ninth Circuit was accordingly wrong in deeming respondents' "limited [marijuana] use [as] clearly distinct" from the broader illicit commercial drug market because "the medicinal marijuana at issue in this case is not intended for, nor does it enter, the stream of commerce." Pet. App. 11a. This Court in *Wickard*, and again in *Lopez*, rejected that very distinction. *Wickard* thus held that Congress could regulate home-grown manufacture of wheat that was not "sold or intended to

be sold," *Wickard*, 317 U.S. at 119, and that "may not be regarded as commerce." *Lopez*, 514 U.S. at 556 (quoting *Wickard*, 317 U.S. at 125). Indeed, the logic of the Ninth Circuit's distinction would prevent Congress from regulating the production and possession—*and even the free distribution*—of *any* controlled substance for *any* personal (including recreational) use, since in that situation, too, the drug "is not intended for, nor does it enter, the stream of commerce" (Pet. App. 11a), at least as the Ninth Circuit conceived of that stream. Thus, it is simply irrelevant that respondents' activities are not commercial in the sense of involving a transaction for consideration, since they do involve economic activity in a class that substantially affects both the market for controlled substances and the effectiveness and integrity of Congress's comprehensive program to regulate that market.

2. The purported medical purposes of respondents' activities do not remove the conduct from Congress's commerce power

The court of appeals also critically erred in relying on the fact that respondents' activities are for purported medical purposes and that Congress's findings in 21 U.S.C. 801 do not specifically address marijuana or the use of marijuana for those purposes. Pet. App. 11a, 19a. Congress's findings are directed at *all* controlled substances, which of course include marijuana. 21 U.S.C. 801, 812(c) (schedule I(c)(10) and (17)). Congress clearly had marijuana in mind in making those findings given Congress's prominent placement of marijuana in schedule I to be "subject to the most stringent controls" and Congress's awareness that marijuana was one of "the most widely abused drug[s]" in the country. H.R.

Rep. No. 1444, *supra*, Pt. 1, at 7, 13; accord S. Rep. No. 613, *supra*, at 2-4.

For purposes of defining Congress's power under the Commerce Clause in enacting the CSA, moreover, there is no basis for distinguishing marijuana production, distribution, or use for purported medicinal purposes, as opposed to recreational (or any other) purpose. To the contrary, as part of its comprehensive regulation of controlled substances, the CSA specifically speaks to the use of controlled substances for medical purposes and the role of physicians in approving their use. For example, whether a substance has an accepted medical use in treatment in the United States is one of the criteria for placement of a controlled substance in schedules I through V, 21 U.S.C. 812(b), and controlled substances generally may be manufactured, distributed, and possessed under the CSA, if at all, only for medical purposes. *E.g.*, 21 U.S.C. 802(21). And where there is an accepted medical use for a controlled substance, the manufacture and distribution of the drug may occur only within the closed regulatory scheme of the Act itself, because of the potential for abuse of and dependence on the drug.

The regulatory scheme imposes registration, labeling, packaging, production, and record-keeping requirements to maintain the safety and integrity of the program, 21 U.S.C. 822-827, and mandates a prescription for dispensing a drug if such a prescription is required by the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. 829. Such regulation of the manufacturing and dispensing of drugs by pharmacies and others for medical use falls squarely within the scope of Congress's powers under the Commerce Clause. The Act also speaks to the role of physicians in dispensing controlled substances. It requires that they be registered under

the CSA to do so, and requires a physician's prescription for dispensing the drug, unless it is directly dispensed by the physician personally. 21 U.S.C. 829.

In short, neither the purported medical use of marijuana nor the role of a physician in approving it provides the slightest basis for excluding it from the comprehensive coverage of the CSA, any more than those factors would support excluding any other controlled substance from the Act. The class of conduct covered by the CSA unquestionably is subject to regulation by Congress under the Commerce Clause because it has a substantial effect on interstate commerce, and Congress plainly had a rational basis for including the manufacture, free distribution, and possession of marijuana for purported medical purposes within that class.

The court was of the view that "concern regarding users' health and safety is significantly different in the medicinal marijuana context, where the use is pursuant to a physician's recommendation," Pet. App. 11a, and that "the limited medicinal use of marijuana as recommended by a physician arguably does not raise the same policy concerns regarding the spread of drug abuse." *Ibid.* Congress has rejected those very propositions. The CSA specifies that marijuana, as a schedule I drug, has "no currently accepted medical use in treatment in the United States," a "high potential for abuse," and "a lack of accepted safety for use" even "under medical supervision." 21 U.S.C. 812(b)(1)(A)-(C).[5]

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[5] The CSA contains provisions under which a controlled substance that has been placed in schedule I (or any other schedule) may be transferred to another schedule or entirely removed from the schedules. 21 U.S.C. 811. In 2001, DEA denied a petition to reschedule marijuana, based on an evaluation of the medical and scientific evidence demonstrating that marijuana continues to

Moreover, even for those controlled drugs that (unlike marijuana) have been determined to have an accepted medical use in treatment and therefore are listed in schedules II through V, the CSA imposes comprehensive restrictions on the manufacture, distribution, and possession of the drugs—including restrictions on physicians and pharmacies—in order to maintain the closed system of distribution and to protect the public health and safety. The court of appeals' decision, by contrast, would place marijuana—a schedule I substance—wholly outside those regulatory safeguards. Thus, the court of appeals' conclusion that the possession, manufacture, and free distribution of marijuana for purported personal "medicinal" use justify excluding those activities altogether from the reach of the CSA is flatly inconsistent with the fundamental premises and purposes of the CSA. Indeed, far from suggesting that the purported medical use of a drug is a basis for excluding it from the scope of regulation under the CSA as a matter of constitutional law, the medical setting for the use of a drug that is subject to abuse provides further justification for its regulation.

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meet the criteria for placement in schedule I. 66 Fed. Reg. at 20,038. The DEA relied in significant part on the medical and scientific analysis by the Department of Health and Human Services (HHS), as well as HHS's conclusions that "[t]here are no FDA-approved marijuana products" and "there have been no studies that have scientifically assessed the efficacy of marijuana for any medical condition." *Id.* at 20,051, 20,052. The DEA previously had rejected a petition to reschedule marijuana in 1992 (57 Fed. Reg. 10,499), and that denial was affirmed by the D.C. Circuit. *Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131, 1137 (1994) ("[T]he Administrator's findings are supported by substantial evidence," including "the testimony of numerous experts that marijuana's medicinal value has never been proven in sound scientific studies.").

The court of appeals' reliance on the purported medical purposes of respondent's drug activities also is inconsistent with this Court's decision in *Oakland Cannabis*. In holding that the CSA forecloses a medical necessity defense to an enforcement action under the CSA, which the Ninth Circuit had embraced, the Court explained that the CSA

> reflects a determination that marijuana has no medical benefits worthy of an exception (outside the confines of a Government-approved research project). Whereas some other drugs can be dispensed and prescribed for medical use, see 21 U.S.C. § 829, the same is not true for marijuana. Indeed, for purposes of the Controlled Substances Act, marijuana has "no currently accepted medical use" at all.

532 U.S. at 491. The Court emphasized that, "[l]est there be any confusion, we clarify that nothing in our analysis, or the statute, suggests that a distinction should be drawn between the prohibitions on manufacturing and distributing and the other prohibitions in the Controlled Substances Act." *Id.* at 494 n.7. In short, the Ninth Circuit purports to give a Commerce Clause basis for effectively re-instating the medical necessity defense that the court of appeals previously adopted in *Oakland Cannabis* based on the same improper rejection of the congressional judgments embodied in the CSA. Because Congress's policy judgments respecting marijuana are reflected in a comprehensive drug statute that regulates the market in controlled substances, the CSA is constitutional as applied to respondents' drug manufacture, distribution, and possession.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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AUGUST 2004